IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA	§	
ex rel. John King & Jane Doe	§	**CIVIL ACTION NO. 06-2662**
and John King & Jane Doe,	§	
individually, et al.	§	
	§	
	§	
Plaintiffs,	§	
	§	
v.	§	
	§	
SOLVAY S.A., et al.	§	
	§	
Defendants.	§	

RELATORS' RESPONSE TO DEFENDANT
SOLVAY PHARMACEUTICALS, INC.'S RENEWED
MOTION FOR PARTIAL SUMMARY JUDGMENT

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RELATORS' RESPONSE TO DEFENDANT SPI PHARMACEUTICALS, INC.'S RENEWED MOTION FOR PARTIAL SUMMARY JUDGMENT

I. INTRODUCTION

A. Short Summary of the Argument.

In order to sway State Medicaid decision makers (generally referred to as P&T Committees) to reimburse Luvox, Aceon, and AndroGel without administrative controls, Solvay Pharmaceuticals, Inc. (SPI) supplied P&T Committee members with various off-label falsehoods about the drugs. SPI was able to gain or maintain favorable placement for its drugs on the state Medicaid drug lists, often called "formularies" or "Preferred Drug Lists" (PDLs). Such improper influence on decision makers is one of Relators' theories of falsity. Relators have never claimed that SPI's campaign was successful in all states for all drugs at all times, and, with the benefit of discovery, have now made concessions where the evidence warrants it.

SPI nevertheless argues, *inter alia*, that, as a matter of law, regardless of coverage status on formularies, PDLs or prior authorization status, Relators' claims must all fail under this theory as to all false claims statutes, both state and federal. This argument hangs on the straw man concept that "drug lists" (such as PDLs) do not affect reimbursability of uses as defined by federal law, and therefore, according to SPI, its actions influencing the content of PDLs has no bearing on any false claims submitted. The Court has already rejected this argument multiple times. In fact, *but for* SPI's dissemination of off-label falsehoods to state Medicaid agencies to keep its drugs free of administrative control, such controls would have blocked most of the reimbursement claims made to these states.

Second, SPI asks the Court to ignore evidence of favorable reimbursement status where that status is bestowed by anybody other than a P&T Committee, arguing that this evidence falls outside of the pleadings and that favorable placement on a "formulary" cannot have happened.

On both counts, SPI purposefully misconstrues Relators' pleadings and fails to account for the realities of the formulary, PDL, and prior authorization systems, as well as Drug Utilization Review (DUR) Board controls and the varieties of ways in which decision makers can choose to block claims for reimbursement, or to freely allow them. Yet SPI did not so distinguish these devices in targeting these decision makers for influence; like Relators' pleadings, they used common terms like "preferred" and "formulary" interchangeably throughout the relevant period.

B. Nature and Stage of the Proceeding.

Relators sued SPI in 2003 asserting claims under the False Claims Act (FCA) concerning SPI's illegal off-label marketing of three drugs: AndroGel, Aceon, and Luvox. Among other claims, Relators have also alleged violations of the Anti-Kickback Statute in furtherance of SPI's illegal marketing. The current live pleading is the Fifth Amended Complaint (5AC). The Court has ruled on multiple motions to dismiss by SPI, as described in more detail below, most recently on August 29, 2012. On November 20, 2013, SPI filed its Motion for Partial Summary Judgment (the MPSJ). ECF No. 232-233. On December 23, 2013, Relators filed Relators' Responses to SPI's MPSJ (the Response). ECF Nos. 241–242. Relators simultaneously filed a Rule 56 Motion for Additional Discovery Time on the basis that the MPSJ was premature because of the incomplete state of discovery. ECF No. 239. Most recently, the Court ordered SPI to re-draft and re-file a motion for summary judgment in light of the plethora of new evidence adduced. Relators now respond to SPI's Renewed MPSJ (RMPSJ).

At the Court's direction, SPI and Relators conferred regarding the existence of PDLs. Relators no longer assert claims based on the "P&T Committee influence" theory as to the following States and drugs:

A. **Luvox**: Arizona and Nevada;

B. **Aceon**: Alaska, Arizona, Colorado, DC, Indiana, Maine, Massachusetts, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Ohio, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Washington, and Wyoming; and

C. **Androgel**: Arizona, Alaska, Georgia, Idaho, Illinois, Iowa, Maine, Massachusetts, Montana, Nevada, New Hampshire, New Mexico, North Dakota, South Dakota, Vermont, and Wyoming.

In addition, as described herein, Relators have narrowed the periods at issue under this theory for each drug in dozens of states.

C. Procedural Background

1. Relators' Claims against SPI

Relators allege in their 5AC that the drug reimbursement claims arising out of SPI's rampant off-label marketing were materially false or fraudulent on several grounds, operating at three distinct levels.[1] Pertinent to this motion, Relators alleged that SPI "actively targeted doctors who were members of states' Medicaid P&T committees and pushed its off-label messages for its drugs in an effort to obtain placement of its drugs on the state Medicaid formularies." 5AC at ¶¶ 287–95. Indeed, a recent deposition of SPI's regulatory personnel confirms that SPI made off-label representations to P&T Committees because SPI's regulatory representative took the position that off-label marketing rules did not apply to interactions between P&T Committees and SPI:

> Q. And what efforts, if any, were made to make sure that the [Medicaid] dossiers stayed on label?

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[1] First, SPI caused physicians to write prescriptions that SPI knew were not eligible for reimbursement by government health programs because they were off-label and/or not "medically acceptable." Second, to the extent that certain marketed uses were categorized as "medically acceptable" because they were included in DrugDex, a compendium, the inclusion of such uses was the result of SPI's fraud on, or with, DrugDex. Third, SPI improperly influenced government pharmaceutical and therapeutic (P&T) committee members, directly or indirectly, through kickbacks and outright off-label misrepresentations about the drugs at issue, to obtain coverage that would otherwise not have been available. SPI did this using a number of tactics, including suppressing study results and placing key researchers under confidentiality obligations, whereby they were prevented from making any statement that would negatively impact SPI's sales.

> A. The dossier did not require staying on label. It's not a promotional piece. It's a medical piece and the—the requirement is very similar to the Compendia. You know, you—you do the literature searches and provide them with a references that can talk about anything with regards to that drug that you have available at that time.

Dep. Tr. [redacted] 283:14–22 (Oct. 23, 2014). Faced with mounting evidence supporting Relators' claims, SPI now argues that Relators' claims regarding SPI's influence on P&T Committees are improperly before the Court. SPI's argument is baseless.

In the 5AC, Relators discussed prior authorization as a sometimes independent means of controlling the drugs throughout the complaint. *See, e.g.*, *id.* at ¶¶ 36, 43. Indeed, as this Court previously summarized, Relators allege that SPI "inappropriately influenc[ed] **which drugs required [prior authorization]** by targeting physicians on state P&T committees . . . ." ECF No. 153 at 54 (emphasis added). Relators allege that not just P&T Committees, but also DUR Boards have, in some states, during some periods, held comparable powers to control Medicaid drug formularies. *Id*. at ¶¶ 39, 41. Relators allege that these efforts were meant to affect state decision-makers in giving the drugs at issue a preferential reimbursement status, thereby increasing the ease with which the drugs would get reimbursed, regardless of "formulary" or PDL status.

2. Prior Rulings on Relators' P&T Committee Theory of Falsity and Materiality.

The statutory seal was lifted in 2010 and SPI was duly served. On December 7, 2010, SPI filed a Motion to Dismiss Relators' Fourth Amended Complaint (the MTD 4AC), in which it argued that Relators' off-label marketing causes of action could not be deemed false or material under the FCA unless they were based on claims submitted to the government for *non-reimbursable* uses; that non-reimbursability is in essence a necessary element for any off-label marketing claim and that, consequently, duping or bribing state Medicaid agencies to win better formulary coverage could not render a reimbursement claim false or material. MTD 4AC at 15–

18. On October 12, 2011, the Court rejected SPI's proposed requirement that the prescribed use be non-reimbursable. ECF No. 153 at 54 (emphasis added).

On January 6, 2012, SPI—again—asked the Court to dismiss "the claims that [SPI] defrauded DrugDex and state P&T Committee members so that its drugs would be reimbursable under federal healthcare programs because they are not plausible." ECF No. 173 at 9. In particular, SPI objected that "it bears repeating that a drug prescribed for a medically accepted indication (e.g. one supported by DrugDex) is reimbursable, irrespective of its placement on a PDL," even if subject to prior authorization. MTD 5AC at 29. The Court summarily rejected SPI's argument and denied the MTD 5AC on that issue. ECF No. 173 at 9. On November 20, 2013, SPI filed SPI's Motion for Partial Summary Judgment (the MPSJ), ECF No. 233 re-urging, *inter alia*, the same argument. After several rounds of briefing, the Court asked SPI to re-draft its MPSJ in light of the "plethora" of new evidence elicited during that period. ECF No. 298. SPI filed Defendant Solvay Pharmaceuticals, Inc.'s Memorandum in Support of its Renewed Motion for Partial Summary Judgment on Relators' P&T-Committee-Influence Theory (RMPSJ) on October 7, 2014. ECF No. 304.

3. Issues and Standard of Review.

There are two issues before the Court: (1) whether this Court should reconsider its past ruling that a claim may be false if procured through fraud on government decision makers or fraud on or with medical compendia, which the Fifth Circuit reviews de novo; (2) whether Relators' evidence of formulary and PDL status for particular drugs, in particular states, during particular periods, where challenged by SPI, suffices to establish a fact dispute as to whether the drug has favorable status that may later be proved to be the result of SPI's undue influence. SPI has made clear that it is not seeking summary judgment at this time as to any drug, period, and

state in which the drug has favorable status, though the parties differ on what favorable status entails.

II. STANDARD OF LAW

In deciding a motion for summary judgment, the district court must determine whether the pleadings, depositions, answers to interrogatories, and admissions on file, together with the summary judgment evidence, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. PROC. 56(c). When considering a motion for summary judgment, the court must view the evidence in the light most favorable to the non-movant and draw all justifiable inferences in favor of the non-movant.[2] "Doubts are to be resolved in favor of the nonmoving party, and any reasonable inferences are to be drawn in favor of that party."[3] The court should not "weigh evidence, assess credibility, or determine the most reasonable inference to be drawn from the evidence."[4] The court must also disregard all evidence favorable to the moving party that the jury is not required to believe and give credence to the evidence favoring the non-moving party as well as to the evidence supporting the moving party that is uncontradicted and unimpeached.[5] The moving party will not meet its burden of proof based on conclusory "bald assertions of ultimate facts."[6]

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[2] *Williams Time Warner Operation, Inc.*, 98 F.3d 179, 181 (5th Cir.1996); *Quicksilver Res., Inc. v. Eagle Drilling, L.L.C.*, CIV.A. H-08-868, 2009 WL 1312598, at *4 (S.D. Tex. May 9, 2009) (citing *Envtl. Conservation Org. v. City of Dallas, Tex.*, 529 F.3d 519, 524 (5th Cir. 2008)).

[3] *Flower v. Prudential Ins. Co. of Am.*, CIV.A. H-07-1091, 2008 WL 154440 (S.D. Tex. Jan. 15, 2008) (citing *Evans v. City of Houston*, 246 F.3d 344, 348 (5th Cir.2001); *Boston Old Colony Ins. Co. v. Tiner Assocs. Inc.*, 288 F.3d 222, 227 (5th Cir. 2002)).

[4] *Williams*, 98 F.3d at 181; *Flower*, 2008 WL 154440 (citing *Honore v. Douglas*, 833 F.2d 565, 567 (5th Cir.1987)).

[5] *Quicksilver Res., Inc. v. Eagle Drilling, L.L.C.*, CIV.A. H-08-868, 2009 WL 1312598, at *4 (S.D. Tex. May 9, 2009) (citing *Moore v. Willis Ind. Sch. Dist.*, 233 F.3d 871, 874 (5th Cir. 2000)).

[6] *Quicksilver Res.*, 2009 WL 1312598, at *4 (citing *Gossett v. Du–Ra–Kel Corp.*, 569 F.2d 869, 872 (5th Cir.1978); *Galindo v. Precision Amer. Corp.*, 754 F.2d 1212, 1221 (5th Cir.1985)).

III. ARGUMENTS AND AUTHORITIES

A. Relators' Claims Have Always Focused on SPI's Actions to Obtain or Maintain More Favorable Reimbursement Positions (*i.e.* Fewer Administrative Controls).

In the 4AC, Relators alleged that SPI engaged in improper off-label marketing, wooing, and misleading campaigns directed at decision makers (P&T Committees) to obtain or maintain favorable reimbursement status for their drugs. 4AC at ¶¶ 281–290. The Court allowed Relators to re-plead certain claims, although not to add supplemental ones. ECF No. 153 at 131 ("No additional claims shall be added."). With the Court's permission, Relators re-pled certain claims, revised others to add more detail, and sent the Court a highlighted version of the 5AC to denote the portions Relators had added or changed. Ex. 224. Among those revisions, Relators expanded on the types of decision makers in the drug reimbursement system and noted the role of DUR Boards.

At the time, neither the Court nor SPI objected to the revisions. SPI now claims as its first reason to ignore copious evidence of preferential status that arguments pertaining to DUR Boards are not "properly" before the Court because they constitute a new claim. On the contrary, Relators' claims were always about SPI's efforts to influence decision makers of all types, including DUR Board members, to obtain preferential reimbursement status throughout the relevant period. 5AC ¶¶ 287–295.

B. Formularies Existed Prior to the Implementation of PDLs.

SPI's argument that technically there *were* no formularies—because States did not enact CMS-approved formularies--is a fabricated construct convenient to SPI's position but entirely irrelevant to Relators' case against it. As reflected in SPI's documents, employees used the term "formulary" to refer to any "drug list" used by States to control conditions of drug

reimbursement. Indeed, although SPI may now choose to ignore the meaning of that term, its employees used it freely throughout the 90s and early 2000s.

For example, SPI employees used the term "formulary" when communicating with physicians. In January 2000, SPI employees (including Regulatory Affairs and Legal Counsel) approved a cheat sheet titled "Treatment Authorization Request (TAR) Process," listing possible "medical justifications" to "assist pharmacists in processing a TAR", including, "Inadequate BP control on a ***formulary (list)*** drug," "Patient cannot tolerate ***formulary (list)*** anti-hypertensive due to side effects (list); Patient was not compliant on ***formulary (list)*** anti-hypertensive." Ex. 50 at SOLCID159200 (emph. added).

SPI employees also used the term "formulary" internally in business plans and "Plans of Action." For example, SPI employees were tasked with "[m]onitor[ing] Medicaid formularies and lobby[ing] for formulary inclusion of [SPI's] products . . . ." Ex. 242 at Kpro-5147. In a 2002 "Report on Events from Field personnel [*sic*] other than DM & Reps," SPI reported that "Illinois is the latest state to pursue closed Medicaid ***formulary***." *Id*. at Kpro-8298 (emph. added). In a Dallas District Business Plan Summary Presentation, SPI employee Tim Stoops reported under "District Challenges," "Tenncare, Managed Care ***formulary*** shutouts." Ex. 39 at Kpro-5919 (emph. added). Indeed, SPI employees strived to have SPI drugs placed "on ***formulary.***" In 2004, SPI noted in a Business Plan that it had obtained "several key Managed Care wins" including, "Florida Medicaid added AndroGel to ***formulary*** in October 2003." Ex. 57 at SPI126345 (emph. added). Florida only enacted a PDL-implementing statute the next year. Ex. 379.

Based on these documents, and the state-by-state examples included below, SPI's employees and the States themselves used the word "formulary" in the same way Relators use it

now: to connote a list reflecting a determination by the State as to which administrative controls, if any, the State would impose on drug reimbursement. The record is replete with further examples.

C. PDLs Are Not the Sole Way to Determine Drug Reimbursement Status.

Contrary to SPI's argument that PDLs are the sole way to determine a state's reimbursement of a drug, and thus that regardless of what was pled, evidence outside of PDLs and P&T Committees should be ignored, states restrict drugs in a variety of ways, including but not limited to prior authorization, drug utilization review (DUR), formularies, *and* PDLs. Ex. 301. And in fact, the bodies that regulate government healthcare drug-reimbursement policies bear a number of names, including P&T Committees and DUR Boards. This is only further complicated by the fact that drug reimbursement is a state-by-state system. Even when focusing only on the narrow mechanism called "PDL," the Nat'l Con. of Leg. states: "Not all states use the term 'PDL,' and the extent of coverage, the process for inclusion and approval, and the enforcement mechanisms vary substantially in some cases." RMPSJ Ex. 6. Despite this and the overwhelming evidence to the contrary, in a gross over-simplification of the country's Medicaid system, SPI claims it is entitled to summary judgment based on the mere existence or non-existence of PDLs and whether or not the drugs at issue were listed on PDLs, when in fact PDLs represent just one means of administrative control of drug utilization employed by the various states.

a. DUR Boards.

DUR Boards are not novel. Under the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), State Medicaid program were required to conduct "drug utilization reviews for all outpatient Medicaid patients." Ex. 256 at 3. As a result, States implemented DUR Boards. For example, Texas' Medicaid Vendor Drug Program "has administered the Texas DUR Program

since it was established in 1992." *Id.* As a result of OBRA '90, State DUR Boards actively controlled, and still control today, drug reimbursement. In fact, DUR Boards do so regardless of a drug's formulary or PDL status by evaluating the criteria for drug coverage within state Medicaid programs.

While the administration of DUR Boards varies from state to state, these Boards are typically composed of physicians, pharmacists, and healthcare professionals who meet to consider and evaluate issues that affect how drugs are provided by the Medicaid program.[7] The State of New York, for example, outlines its DUR Board's responsibilities to include, the "review of therapeutic classes subject to the Preferred Drug Program." Ex. 309. DUR Boards "also determine the prior authorization criteria for drugs with special prescribing guidelines and the prior authorization criteria for non-preferred drugs, those that do not make the PDL." *Id*. DUR Boards therefore impose a number of measures, including step-edits, quantity limits, prior authorization and others. When DUR Boards impose prior authorization on a drug, the state agency's approval becomes necessary to qualify a doctor's prescription for reimbursement as to an individual patient, regardless of whether the drug is listed on a formulary or PDL. *Id*. DUR

[7] *See, e.g.*, Ex. 306 ("The DUR Board provides evaluation of criteria for drug coverage within the Medicaid Program. The Board is composed of Physicians & Pharmacist professionals who meet on a monthly basis to consider issues that affect how drugs are provides by the Medicaid program."); Ex. 307 ("Drug utilization review programs help to ensure that prescription for outpatient drigs are appropriate, medically necessary, and not likely to result in adverse medical consequences. DUR programs use professional medical protocols and computer technology and data processing to assist in the management of data regarding the prescribing of medicines and the dispensing of prescriptions over periods of time. […] The New York Medicaid DURB is comprised is comprised of health care professionals appointed by the Commissioner and includes physicians and pharmacists that actively practice in New York."); Ex. 308 ("Federal regulations 42 C.F.R. §§ 456.703-456.725 require that Medicaid pharmacy programs establish and maintain a [DUR] program that helps to ensure appropriate drug utilization by conducting prospective and retrospective drug utilization review, and maintaining an education program. These regulations also require that state Medicaid pharmacy programs establish and maintain a Drug Utilization Review Board (DUR Board).").

Boards are used to restrict access to drug classes for a variety of reasons, including drugs that have been found to be over utilized, abused, or have significant safety concerns.[8]

DUR Boards' prior authorization authority therefore created and continues to create significant barriers to Medicaid reimbursement. For example, in order to obtain prior authorization for androgens such as AndroGel in Utah today, a physician must provide two morning testosterone levels drawn on different days and use one of two specifically identified diagnosis codes (one for other testicular hypofunction and the other for other anterior pituitary disorders). Ex. 310. In addition, Utah has approximately 130 prior authorization forms specific to therapeutic classes and drugs, but only two that address prior authorization for "non-preferred," *i.e.* not listed as "Preferred on Utah Medicaid's Preferred Drug List." Ex. 376.

Alabama has prior authorization forms for particular conditions as well as drugs. Ex. 377. For example, Alabama has a prior authorization form for: AIDS Wasting Request, Adult Growth, Child Growth Hormone Deficiency, and for biological drugs, belying that the only factor governing prior authorization is whether or not a drug is on the state's PDL. *Id*.

Alaska implemented a DUR Board in 1990 and uses it to respond to actual or potential medication utilization issues such as "safety, fraud, waste, abuse, misuse or medically unnecessary care." Ex. 378. In fact, Alaska has a Prospective and Retrospective DUR. The prospective DUR is performed by all Alaska pharmacists *before* they fill a prescription. *Id*. But Retrospective DUR is conducted by the State's "DUR Committee sometime after a prescription is filled. The committee consists of physicians, pharmacists, and other healthcare providers who are actively practicing in the community, as well as 1 pharmacist . . . ." The DUR committee uses a number of methods to control drug reimbursement, including, "prior authorizations, step-

[8] *See, e.g.*, Ch. 518, Pharm. Svces. of the W. Va. Medicaid Manual.

edits, therapeutic duplication edits and quantity limits." Ex. 378. In order to fulfill its responsibilities, the DUR committee meets at least quarterly to review the use of medications by Medicaid recipients "and identify regimens that do not meet predetermine clinical criteria." Id. These predetermined clinical criteria are not mandated or provided by the PDL. Again, the PDL is only one piece of the drug-control puzzle. It is absurd to claim that PDLs, and only PDLs, determine reimbursement of a drug in any given state for any given time period and SPI's own documents prove this point. Long before the implementation of PDLs, SPI employees recognized the States' power to impose administrative controls, such as prior authorization, on drug utilization.

b. Formularies

Prior to 1990, the Medicaid statute did not specifically address outpatient prescription drug coverage.[9] In 1993, Congress amended the statutes, allowing states to establish their own formularies. 42 U.S.C. § 1396r. As part of this scheme, the federal statute laid out various grounds on which states were authorized to control utilization, such as abuse. *Id*. More formal formularies also went into effect as a result of the federal Medicaid statute, and states adopted a number of individual drug reimbursement systems. While some states had "open" formularies and placed few restrictions on Medicaid reimbursement, other states used prior authorization as a means of controlling drug costs.[10] Further, as to some—but only some—states, if a drug was not specifically included on the list of approved drugs, it would not be reimbursed without prior

[9] *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 651–52 (2003).

[10] *See, e.g.*, Ex. 45 (Luvox . . . is now on all Medicaid formularies nationwide.); Ex. 201; Ex. 48; Ex. 50.

authorization.[11] As discussed above, States enacted drug lists which they used to control drug reimbursement and both the States *and SPI's employees* called such lists "formularies."

c. The PDL System

Starting in 2001, states began adopting and implementing PDLs.[12] A PDL is a list of drugs, organized by drug class, that are deemed preferred by the state for various reasons. [13] P&T Committees, sometimes along with state directed private entities, periodically review drug classes which are made up of drugs with similar chemical compositions and effect. They then decide or recommend which members of the class to include on the PDL.[14] Among drugs in a specific class deemed equally effective, expense is often a factor in which drug or drugs will be designated as preferred.[15] The remaining drugs in that class are then categorized as "non-preferred drugs."[16] In addition, when a PDL law is passed in a state, the P&T Committee begins a therapeutic class review. There can be large numbers of therapeutic classes, sometimes exceeding 70, and it often takes years to evaluate all of the drug classes. In the meantime, no interim controls are added or imposed. Regardless of P&T Committee activity, DUR Board controls function independently.

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[11] *Walsh*, 538 U.S. at 651–52 (describing GA's and CA's Medicaid program) *Dodson v. Parham*, 427 F. Supp. 97, 100–101 (N.D.Ga.1977) (GA has historically administered its prescription drug program on the basis of a drug 'formulary' or, in other words, a restricted list of drugs for which Medicaid will reimburse provider pharmacists. Thus, any drug not specifically included on the list will not be reimbursed unless prior approval is granted by [the administrator of Georgia Medicaid program]); *Cowan v. Myers*, 187 Cal.App.3d 968, 974–975, 232 Cal.Rptr. 299, 301–303 (1986) (describing 1982 CA law providing that certain drugs would be covered under CA Medicaid program only after prior-auth).

[12] Relators note that SPI's insistence that Luvox was never listed on a PDL and therefore Relators' claims must fail is disingenuous given that Luvox was taken off the market just as PDLs began to be implemented. It would be a legal impossibility, in most States, for Luvox to be on PDL because PDLs did not yet exist. However, formularies did, and the evidence is overwhelming that SPI wooed and lied to States to obtain preferential formulary status for Luvox.

[13] *Grier v. Goetz*, 402 F. Supp. 2d 876, 899-900 (M.D. Tenn. 2005) *order clarified*, 421 F. Supp. 2d 1080 (M.D. Tenn. 2006) (internal citations omitted).

[14] *Grier* at 900 (internal citations omitted).

[15] *Id.*

[16] *Id.*

D. The Record is Replete with Further Examples Belying SPI's Arguments That "Formularies" Never existed and that PDLs Are the Sole Measure of Reimbursement Status.[17]

Below, Relators include a few states that further exemplify the absurdity of SPI's semantic argument that "formularies" didn't exist and that PDLs are the only way to determine drug reimbursement status. When citing SPI documents, Relators have reflected SPI's choice of terms.[18]

a. Androgel

1. Colorado

In 2000, according to SPI's documents and in its own words, AndroGel was already "on formulary" in Colorado. Ex. 289. From 2001 to 2002, however, though no PDL was yet established, Colorado's Medicaid program subjected AndroGel to prior authorization. Ex. 68, 272, 293; Ex. 294 at 34. In 2004 and 2005 Colorado was certainly covering AndroGel without prior authorization; utilization rose steeply. Ex. 201 at 71, Ex. 183, Ex. 201 at 71. Colorado finally implemented a PDL in 2007. Ex. 288. Based on the evidence and utilization, SPI referred to drug reimbursement control lists as "formularies" prior to implementation of PDLs in Colorado. And Colorado apparently used prior authorization to control reimbursement, also prior to implementation of PDLs.

2. Louisiana

Louisiana's Medicaid program's history of reimbursement for AndroGel is a counterexample: it demonstrates the coverage and utilization trajectory for AndroGel if fully

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[17] In assuming that PDLs are the dispositive issue for Relators' P&T Committee theory, SPI fails to address Relators' actual allegations. The 5AC discusses DUR Boards or Committees, prior-auth, and improving formulary placement generally, as well as P&T Committees and PDLs. 5AC at ¶¶ 39, 41, 287-295. Further, prior to PDLs, states used a formulary system to determine which drugs would get reimbursed. As to formularies, Relators specifically alleged that, "[SPI] sales representatives attended P&T committee meetings when permitted in an effort to obtain formulary placement." *Id.* at ¶ 292.

[18] Additional state-by-state analyses are included in App'x B, C, D.

covered. Louisiana passed a law authorizing the establishment of a PDL in 2000 and passed another law in 2004 requiring the P&T Committee to review drugs prior to inclusion on the PDL. Ex. 288 at 295. Despite the existence of PDLs, SPI's documents reflect that in 2000 SPI referred to AndroGel as "on formulary" in Louisiana. Ex. 289. In 2002, AndroGel was covered without restrictions. Ex. 249 at 72, Ex. 68. In 2003, although androgens as a class were *not* on the PDL, AndroGel was available without restrictions. Exs. 164, 272, 290, Ex. 60 at 289. This continued through 2004 and 2005. Exs. 183, 184, 291, 165, Ex. 201 at 69. That alone belies SPI's theory that PDL are the dispositive issue in determining reimbursability.

In August 2006, the Louisiana P&T Committee reviewed the androgenic agent therapeutic class for the first time and gave AndroGel preferred status. Ex. 6 at LADHH-4020. The Committee also voted to keep AndroGel a preferred product at the August 2007 meeting. Ex. 109 at LADHH-1803. Both times, the P&T Committee reviewed clinical information presented by Provider Synergies, which contained statements such as, "Symptoms of this disorder include impotence, decreased libido, fatigue, loss of energy, mood depression, and regression of secondary sex characteristics," and "Treatment goals are to allow patients to function normally as well as decrease the risk of secondary complications such as fertility, osteoporosis, fatigue, and mood disturbances." Ex. 197 at 2660, Exs. 65, 75; Ex. 198 at 3170. SPI generally provides clinical data to Provider Synergies, and it is highly likely that these misrepresentations of AndroGel's indication originated from SPI, as was the case with Aceon in Illinois. *See e.g.*, Ex. 178. AndroGel remained preferred from 2006 to at least 2008. Ex. 110 at 4888; Ex. 6 at 20; Ex. 15 at 5205; Ex. 109 at 1803; Ex. 111 at 606. Utilization grew from 2000 to 2005. App'x A.

3. Maryland

Maryland's Medicaid reimbursement history with respect to AndroGel is similar to Louisiana's and also exemplifies drug reimbursement and utilization when a drug remains covered. In SPI's words, AndroGel was "on formulary" in Maryland in 2000. Ex. 289. In 2002 AndroGel was still covered without restrictions. Exs. 68, 249 at 72. Maryland implemented a PDL in 2003 but continued to cover AndroGel without restrictions despite the fact that AndroGel's therapeutic class was not on the PDL. Ex. 288 at 295; Exs. 290, 272. In 2004, AndroGel was reimbursed as a 3rd Tier drug, probably subjecting it to prior authorization. Exs. 184, 291. In 2005, Maryland's Medicaid program reimbursed AndroGel without prior authorization. Ex. 201. Finally, AndroGel became preferred in 2006 and 2007. SPI MSJ Exs. 242-243. In August 2007, following SPI's presentation regarding AndroGel at the Maryland Medicaid P&T Committee meeting, the Committee voted to retain AndroGel as the only testosterone gel on the Maryland Medicaid PDL. Exs. 228-229. SPI Regional Account Manager [redacted] acknowledged this "win." Ex. 229. First, based on the evidence, SPI clearly referred to drug reimbursement control lists as "formularies." Second, SPI did so prior to the implementation of PDLs.

4. Mississippi

In 2000, AndroGel was "on formulary" in Mississippi. Ex. 289. In 2002, Mississippi's Medicaid program covered AndroGel without restrictions. Ex. 249. In 2004, Mississippi enacted a Medicaid omnibus bill directing the Medicaid division to establish a mandatory preferred drug list. Ex. 288 (citing HB 1434). Yet, SPI documents indicate that both in 2003 and 2005, AndroGel was available without restrictions even though its therapeutic class was *not* on the PDL. Ex. 60, 201. It is unclear what the 2003 documents refer to, given they predate the supposed enactment of Mississippi's "mandatory preferred drug list." This underscores the

problem with focusing on form—as SPI wants the Court to do—rather than substance when trying to understand drug status. First, the evidence show that SPI referred to drug reimbursement control lists as "formularies."

5. New York

New York is an excellent example of situations where drugs are not included on the PDL but enjoy favorable reimbursement status, which translates into significant utilization. SPI's documents reflect that in 2000 New York had an "open formulary," using SPI's words, whereby AndroGel was reimbursed without prior authorization. Ex. 289. In 2005, New York authorized the creation of a PDL. Ex. 288 (citing S 3668). Yet, according to documents produced in this litigation, from 2002 to 2008 androgenic agents were not on PDL. Exs. 249, 68, 290, 272, 183, 51, 298. During that period, and despite the omission of androgenic agents from the PDL, New York's Medicaid program reimbursed AndroGel and did so without prior authorization. *Id.* In fact, utilization skyrocketed after 2001, staying over $2 million annually in 2003, 2004, and 2005. Based on the evidence and Medicaid utilization, New York reimbursed AndroGel without administrative controls, and despite the fact it was not included on the state's PDL for six years, from 2000 to 2008. This is not a singular event; drugs are commonly not included on a PDL during transition periods (which can last for years) because a particular class has not yet been evaluated by the P&T Committee. However, during those periods, drugs belonging to those classes often continue to enjoy favorable reimbursement treatment.

6. Ohio

SPI's documents reflect that in 2000 AndroGel was on Ohio's Medicaid "formulary." Ex. 289. But by the start of 2001, AndroGel was no longer on formulary. Ex. 67 (covered intermittently in 2001). SPI also aggressively lobbied Ohio Medicaid to include AndroGel on

Ohio's Medicaid formulary without prior authorization requirements by touting off-label uses of AndroGel and relying on dubious scientific studies.

In May 2001, [redacted], Senior Representative for Government Affairs at SPI, circulated an email regarding "OH AndroGel presentation." Ex. 216. SPI's strategy included sending an Opinion Thought Leader, such as Dr. Eric Sorono, who saw Medicaid patients and prescribed testosterone for "body building," to promote AndroGel's reimbursement by Ohio's Medicaid program. *Id.* SPI employee Soozi Hamilton wrote to Regional Account Executive [redacted] in a May 2001 email and stated, "I saw an old friend last week…Bob Reid! He is still working for the Medicaid office and still has decision-making authority with Medicaid formulary." Ex. 217. Reid told Hamilton that SPI should discuss AndroGel's "clinical significance and superiority" versus other androgen products at the next P&T Committee meeting. *Id.* In June 2001, [redacted] emailed [redacted] informing her that he had secured a speaker to present AndroGel information to Ohio's P&T Committee. Ex. 218. Mr. [redacted] also suggested that an Opinion Thought Leader write a letter to be included in the packet sent to each P&T member. *Id.* In addition to these efforts, one month later, in July 2001, [redacted], [redacted]s successor as President of Unimed, sent a letter to Bob Reid. Ex. 62. The letter, which was approved by Regulatory, fails to mention hypogonadism and discusses AndroGel's purported effects on body mass, bone mineral density, libido, mood, and fatigue. *Id.*

SPI's first round of efforts was successful. By the end of 2001, AndroGel went from being subject to prior authorization to being reimbursed without prior authorization. Ex. 67 at SPI364906. In 2002, as part of the state's budget bill (§ 5111.082), Ohio empowered its Medicaid authority to implement a supplemental drug rebate program and "make drug manufacturers not making such payments subject to prior authorization." The bill did not use the

term "preferred drug list" despite creating, and using, administrative controls before and after this bill. Ex. 288 (citing SB 261 (2002)). In a March 11, 2002, internal email [redacted] of SPI reported, "Presentation to state Medicaid P&T Committee's [sic] to remove prior authorizations. ***This was successful in Ohio.***" *Id.* (emphasis added). Unfortunately for SPI, by 2003 AndroGel was again subject to prior authorization. Ex. 219 at 141. It is unclear at what point Ohio implemented a PDL.

As a result of this reversal, SPI went back on the offensive, and "developed" a certain Dr. Elena Christofides to serve as an "Endo AndroGel Speaker and OH Medicaid." Ex. 75 at SPI469559. Indeed, on October 5, 2003, [redacted] SPI met with Dr. Christofides to discuss "AndroGel & Ohio Medicaid." Ex. 208. On January 20, 2004, [redacted] circulated an email discussing the "key points" that Dr. Christofides was going to cover at the Ohio P&T Committee meeting, and nowhere does [redacted] mention hypogonadism. Ex. 209.

Dr. Christofides appeared at the Ohio P&T Committee meeting shortly thereafter and succeeded in convincing the Committee to lift the prior authorization requirement for AndroGel while leaving it in place for AndroGel's competitor products, Testim, Striant, and Androderm. Exs. 210, 211. SPI employees circulated an email congratulating [redacted], SPI Corporate Account Executive, "for his efforts in securing this win." Ex. 210. [redacted] apparently did so in two ways. First, he had "a special relationship with the Medicaid director Bob Reid and was able to secure time for two SPI products to get review." *Id.* Second, SPI was able to secure a "10-minute presentation by Dr. Christofides, Endocrinologist, which turned in to a 30-minute detail and Q&A outlining the cost benefit . . . ." *Id*. With SPI's coaching, Dr. Christofides told the P&T Committee about "symptoms of low t such as depression," "depression and the impact of Osteoporosis on the elderly male," and "the cost of Injection vs. AndroGel based on the

pharmacoeconomic model- *provided by* [redacted] *and fine tuned by Dr. Christofides*." Ex. 212. SPI's coaching and Christofides' off-label claims regarding AndroGel paid off in a big way: AndroGel did not require prior authorization for Ohio Medicaid reimbursement through at least 2008. Ex. 51 at 542, Exs. 163, 299, 300, 3, 51. This is despite the fact that at least as of 2004, androgens were *not* on Ohio's PDLs. Ex. 163. Utilization, not surprisingly, grew from 2001 through 2005. App'x A.

7. South Carolina

SPI's documents indicate that in 2000, South Carolina's Medicaid program had AndroGel on formulary. Ex. 289. From 2002 through at least 2005, South Carolina's Medicaid program reimbursed AndroGel without restrictions. Exs. 12, 57, 59, 213, 249, 268, 68, 290, 272, 59 at 132179. South Carolina then implemented a PDL in 2004. Ex. 288. Of relevance is the fact that when South Carolina did have a PDL, androgenic agents were not on it, and yet were reimbursed without prior authorization. Ex. 96. South Carolina Medicaid only added the androgenic agent class to its PDL in 2008 and that is when it first designated AndroGel a preferred product. Ex. 202.

b. Luvox

1.California

Although most states did not implement a PDL until after 2000, SPI states that California implemented a PDL in 1991. MPSJ at 7. SPI made significant efforts to convince Medi-Cal to add Luvox to its **formulary**, which initially opposed adding Luvox without prior authorization due to what it deemed Luvox's "misuse potential," as reflected in SPI's letter to Medi-Cal dated August 1995, which states, "The Upjohn and SPI companies would like to have the opportunity to better understand your action to restrict the use of LUVOX based on 'misuse potential.'" Ex. 245.

A November 1995 draft letter from SPI to Medi-Cal begins as follows, "This package of information on LUVOX tablets is being submitted to assist you in your therapeutic review of an anti-depressant drugs. [sic]." Ex. 246 at 113. In April the following year, SPI asked Dr. Herbert Hendin of the American Society for Suicide Prevention, to send a letter to Medi-Cal supporting inclusion of Luvox. Ex. 316. SPI's efforts were to no avail. The April 1996 minutes of the SPI Management Committee meeting note that California still refused to cover Luvox on Medi-Cal without prior authorization and SPI subsequently appealed. Ex. 66 at 124. *See also* Exs. 72, 247.

According to a November 1996 memo to [redacted], President of SPI, "The [Medi-Cal] Department would reconsider the addition of LUVOX . . . Tablets to the Medi-Cal formulary in the event that a new indication was received or significant new clinical information became available . . . we will continue to pursue the objective of having LUVOX Tablets available for use in Medicaid patients in California without the requirement of prior authorization." Ex. 72 at 67. Such "new information" would consist of data "being collected from Canada where use in both indications (depression and OCD) should show a reduced daily consumption compared with the number used" to make prior representations to Medi-Cal. *Id.* Ultimately, SPI made numerous off-label misrepresentations about Luvox to Medi-Cal to convince it to change its mind. On April 1, 1997, SPI sent a letter to the Chief of the Medi-Cal Contracting Section, Janet K. Howard, responding to Medi-Cal's interest in any new indication. Ex. 248. Rather than informing Howard that the FDA had *twice* rejected SPI's application for a depression indication based on insufficient proof of efficacy, SPI urged the consideration of Luvox's efficacy in treating depression. *Id.* at 648-649, 5AC ¶¶ 65-67; Exs. 273, 230. SPI's letter was accompanied by a binder containing multiple depression studies and even studies on autism and selective

mutism. Ex. 265, 266 (binder cover and contents respectively). SPI sent the same letter and binder to another Medi-Cal decision-maker, Cindy Giambrone, on April 22, 1997. Ex. 182.

A number of SPI employees targeted Medi-Cal P&T Committee members in April 1997. *See* Ex. 231-238. Medi-Cal was not duped by this technique and was well aware that the letters from a myriad of authors all came from SPI. In fact, in May 1997, Adrian Wong of Medi-Cal told SPI he wished they "would not send any letters," because last time SPI had gone before the Medi-Cal committee, it had received over 100 letters. Ex. 239. SPI's lobbying paid off: a September 11, 1997, press release announced that Medi-Cal would add Luvox to its formulary effective October 1, 1997. Ex. 240; Ex. 45 at 75; Ex. 317 at 16. This was no small feat given that "Medi-Cal [wa]s the largest state Medicaid program in the United States." *Id*. Not surprisingly, utilization was maintained at about $150,000 to $190,000 per quarter until Luvox gained its favorable status in September 1997, after which utilization rose steeply, peaking at over $1.3 million in the last quarter of 2000.

2.Illinois

In February 1995, Illinois's Medicaid program subjected Luvox to prior authorization. Ex. 70. SPI's documents show that by 1997, SPI considered Luvox to be "on formulary" in Illinois. Ex. 45 at 75. Utilization kept growing until the introduction of generics in 2000. Illinois implemented a PDL in 2002. Ex. 288 at 294-5. SPI's documents indicate that Luvox retained its preferential status in 2002 and 2003, when Illinois reimbursed Luvox without prior authorization. Exs. 249, 290, 272. Based on the evidence and utilization, Luvox was available in Illinois without administrative restrictions from 1996 to 200h3, and independent of the existence of PDLs. Indeed, if the Court were to ignore the existence of formularies—as SPI has requested—it would be ignoring a very well documented battle by SPI to obtain favorable reimbursement status.

3.Kentucky

In 1995, SPI's documents reflect that Luvox was not reimbursed by Kentucky's Medicaid program. Ex. 70. But SPI changed that by using Dr. Douglas Rank's services. On August 18, 1995, Dr. Douglas Rank made a presentation to Kentucky's P&T Committee regarding Luvox. Ex. 250 at KY-HFS984-995. Dr. Rank told the Committee, "Luvox is an antidepressant" and "It's not specific just for OCD. It would treat depression." *Id.* at 992. Dr. Rank also stated, "Body dysmorphic disorder is treatable with Luvox," "It's frequently seen in Tourette's Syndrome and is a comorbid condition" *Id.* at KY-HFS985. Dr. Rank even went so far as to imply that adding Luvox to Kentucky's formulary would decrease the amount the state spends incarcerating people for theft; Dr. Rank stated, "There's research on kleptomania in Cincinnati. This, of course, is an enormous cost. If people get caught stealing, they go to jail. It's a high cost to society." *Id.* at KY-HSF991. Dr. Rank has an ongoing financial relationship with SPI – for instance, SPI paid Dr. Rank $100.00 for a consultation expensed as "Other Promotion" in July 1996. Ex. 251 at SPI73. SPI's efforts off-label efforts and false pretenses paid off. SPI's documents reflect that in 1996, Kentucky began reimbursing Luvox without prior authorization. Ex. 43 at SOLCID15256. In fact, in May 1996, SPI Regional Marketing Manager [redacted] circulated a triumphant memo announcing the fact that Luvox would soon get Medicaid approval "without prior authorization" in Kentucky. 5AC Ex. 43. *See also* Ex. 252 (produced by Kentucky). SPI had reason to pat itself on the back; in 1996 utilization skyrocketed from $87,631 to $407,631. App'x A.

SPI's documents and evidence of Medicaid utilization in Kentucky reflect that SPI's actions had long-term consequences. In 1997, Luvox was "on formulary" in Kentucky. Ex. 45 at 75. Kentucky implemented a PDL in 2002. Ex. 288 at 295 (citing HB 103). Although in 2002 Kentucky placed some restrictions on reimbursement, those were gone by 2003. Ex. 290, 272,

249 at 72. Utilization continued to grow through 2000. In 2001, with the introduction of generics, utilization dropped to $496,595, and then it dropped precipitously to $147,994 in 2002. App'x A. Based on the evidence and utilization, Luvox was available in Kentucky without administrative restrictions from 1996 to 2001 and in 2003. It is also evident that Kentucky's Medicaid program was imposing coverage restrictions long before the enactment of its PDL law in 2002.

4.Texas

SPI's documents reflect that in 1995, Texas reimbursed Luvox without prior authorization. Ex. 70. And Texas Medicaid continued to not require prior authorization for Luvox in 2002 and 2003. Exs. 183, 184, 249, 272, 290. Utilization grew from 1995 to 2000 and stayed over $1 million in 2001. This lack of administrative controls, and resulting utilization, was the result of deliberate choices by Texas' Medicaid program. For example, in 1996, Texas' Medicaid program developed administrative controls for ace inhibitors. Ex. 255. Texas could have, but chose not to, subject a mental health such as Luvox to similar controls. In 2003, the Texas governor approved the establishment of a PDL that would only contain "drugs provided by a manufacturer or labeler that reache[d] an agreement with the commission on supplemental rebates." Ex. 288 (citing HB 2292 (TX) (2003)). It is therefore clear that Texas chose to make Luvox available without administrative controls before PDLs.

c. Aceon

States throughout the nation controlled Aceon Medicaid utilization by imposing administrative controls, such as prior authorization. SPI was well aware of this and actively targeted P&T Committees to discourage implementation of such control mechanisms. For example, on October 4, 1999 SPI circulated a Supplement published by the American Journal of Managed Care to no less than **28,400** P&T Committee members. Ex. 186. Internally, SPI noted

that the Supplement was "an excellent review of Arterial Wall Compliance (AWC) issues and also contain[ed] information on perindopril [Aceon]." *Id.* at 88. In fact, the Supplement contained articles on four talks and a list of selected abstracts. Ex. 186. Three of the four talks touted Aceon's AWC benefits, as did one of the selected abstracts. *Id*. Such representations were off-label and misleading. In fact, three months earlier DDMAC had expressly told SPI that it considered SPI's "presentation of claims and representations related to arterial compliance to be misleading." 5AC Ex. 19. Fully aware of this, SPI's memo *announcing* the distribution of the Supplement to *28,400 P&T Committee* members by SPI ***also*** contained the following disclaimers:[19]

For your information only. Not to be shown to or discussed with healthcare professionals.

For your information only. Not to be used for detailing or in any promotional manner.

1. Alabama

SPI's records reflect that Aceon was an "approved" drug in Alabama in 2000. Ex. 48. Aceon was "preferred" in 2002 and "covered without restrictions" in 2003, prior to implementation of a PDL in Alabama, which took place in 2003. Ex. 41 at 904; Ex. 39 at 5943; Ex. 60 at 89; Ex. 290 (2003); Ex. 272; Ex. 288 at 293. This was no accident.

In a February 2002 business plan for the Birmingham District, District Manager [redacted] stated that he had, "[w]ork[ed] with State P&T Chairman to have Aceon included on preferred ACE inhibitor list . . . ." Ex. 39 at 943. Birmingham sales representative [redacted], after attending a March 2002 P&T Committee, Ex. 41 at 903. reported to [redacted] that she had discussed Aceon and SPI's misleading sales pitch regarding the off-label PROGRESS study with Dr. 48, then Chairman of the P&T Committee for Alabama Medicaid,

[19] Ex. 60.

and had learned that he favored it for stroke patients on that basis. *Id*. SPI's improper influence in Alabama then continued into the PDL era. Alabama implemented a PDL in 2003. In anticipation of the P&T Committee's review of Aceon in August 2003, SPI Regional Account Executive [redacted] met with Dr. 48, provided him with a binder containing results from the ACT trial, and discussed "Aceon's advantage of 24 hour control of blood pressure." Ex. 318. Dr. 102, who had also heard [redacted] PROGRESS pitch and had invited her to the 2002 meeting, became Chair of the P&T Committee in 2003, which then granted Aceon preferred status. Aceon remained "Preferred" from 2004 through at least 2008. *Id*. Consistent with this, utilization grew from 2000 to 2003 and peaked in 2005.

2. Delaware

According to SPI's documents, as of 2000, Aceon was an "approved" Medicaid drug in Delaware. Ex. 48. Furthermore, SPI's documents show that Delaware's Medicaid program covered Aceon without restrictions from 2002 to 2004 and for a portion of 2006. Ex. 249 at 72; Exs. 183, 184, 272, 290, 291; SPI MPSJ Ex. 57. In 2005, after the implementation of a PDL system, Aceon became subject to administrative controls. Ex. 288 at 294. This crystallizes the fact that PDLs, by themselves, are not the start or the end of the inquiry and that states can choose to control drug reimbursement in a variety of ways. Utilization of Aceon in Delaware was in accord with its regulatory history: it grew gradually from 2000 to 2004 and plummeted in 2005.

3. Florida

According to SPI's documents, in 2000, Aceon was a Medicaid "approved" drug in Florida. Ex. 48. Florida implemented a PDL in 2001. Ex. 288 at 294 (citing SB 792 (2001)). Unfortunately for SPI, in 2001 Aceon became subjected to prior authorization, and in 2002, Florida's P&T Committee "locked out" Aceon from Medicaid reimbursement. Exs. 319, 320 at

37. As a result, SPI relentlessly targeted Florida Medicaid in an effort to secure advantageous positioning for its products and even tried to hand-pick P&T Committee members. *See* Exs. 321, 322.

SPI's 2001 plan explained how SPI could distinguish Aceon from other hypertension drugs: "by using the PROGRESS data to leverage a true 'Medical Need' for those patients that have a family history of stroke. Since there are number [sic] of medications for hypertension on the Preferred Drug List, it is imperative that we identify a true 'medical need' for ACEON." Ex. 191 at 64. Furthermore, in response to the Florida Agency for Health Care Administration's (AHCA) public statements about "looking for tangible savings for the Medicaid budget," the plan proposed offering AHCA a value-added program of "stroke education" to Florida Medicaid recipients. *Id*.

On August 25, 2001, the P&T Committee reviewed ACE inhibitors, and SPI Medical Liaison [redacted] presented PROGRESS data to the committee. Ex. 192. The Committee elected not to add Aceon as a preferred product, and [redacted] sent an email stating, "While we knew we'd not be added to the formulary at this meeting, we did succeed in the difficult task of capturing AHCA's interest in Aceon. . . . I understand that [redacted] did an outstanding job at presenting some info on Progress and piquing AHCA's interest in pursuing this matter further with a presentation to Provider Synergies.[20] We are optimistic about this opportunity and are pursuing it aggressively." Ex. 192. SPI Medical Liaison [redacted] presented the PROGRESS data to Provider Synergies on October 17, 2001, and SPI's internal Florida Medicaid "work group" met regularly "to evaluate and implement other strategies to maximize [Aceon's] market potential." Ex. 187 at 19; Ex. 193 at 73. One Florida District

[20] Provider Synergies was the Pharmacy Benefit Manager for Florida's Medicaid program and charged with providing clinical information and recommendations to the P&T Committee regarding therapeutic classes under review.

Manager, [redacted], instructed his sales representatives to make a point of calling on P&T Committee members to pitch Aceon. Ex. 323. One of Flower's sales representatives, [redacted], called on P&T Committee member Dr. Robert Blackburn and at the end of the sales call, Dr. Blackburn told [redacted] that he would try Aceon. *Id.* [redacted] scheduled a lunch n' learn in Dr. Blackburn's office and told his district manager, "hopefully by then we will have progress [data] to leave." *Id*. Another one of Flower's sales representatives, [redacted], scheduled a lunch n' learn with P&T Committee member Dr. Craig Trigueiro, who expressed interest in Aceon and requested Aceon samples after hearing Trigueiro's spiel about Aceon offering "true 24hr. blood pressure control," a claim that Trigueiro had not previously heard. *Id.*

In February 2002, SPI Senior Government Affairs Representative [redacted] wrote to a team of fellow Government Affairs employees to discuss the "FL MEDICAID Aceon Opportunity Meeting." Ex. 180. In his email, [redacted] explained that he, other SPI employees, and SPI lobbyists met with "Florida's Medicaid Pharmacy Chief, George Kitchens, R. Ph. and ACHA Chief of Staff, Travis Blanton. *Id*. During that meeting, SPI was assured that Aceon would be reconsidered for addition to the PDL at the P&T Committee's March meeting after an initial PDL rejection. *Id*. [redacted] described this as a "golden opportunity to make a case for Aceon to the P&T. . . ." *Id*. [redacted] explained that this was the time to review SPI's "Aceon proposal to FL Medicaid (via presentation to Provider Synergies) and consider submitting a new offer." *Id*.

In 2002, [redacted] laid out a plan titled, "2002 Florida Medicaid Action Plan, The Action Plan for ACEON Approval for Florida Medicaid PDL." Ex. 181. The plan featured prominently claims based on PROGRESS trial that Aceon could prevent a second stroke, noting that Kitchens was "compelled by the PROGRESS data. . . ." *Id.* at 2. SPI's leadership was aware that

PROGRESS did not support a finding that Aceon is more effective at preventing secondary strokes than other ace inhibitors. However, having heard SPI's misrepresentations Florida began reimbursing Aceon without prior authorization in 2003 and continued to do so for most of the time period through 2007. Exs. 47, 116-131. Utilization was greatly benefited by this. While utilization had reached nearly $100,000 in 2001, and then plummeted in 2002 due to the "lock out," by 2004 it was over $200,000 annually.

4. Kentucky

SPI's documents reveal that in 2000, Aceon was a Kentucky Medicaid "approved" drug. Ex. 48. On November 14, 2002, SPI Medical [redacted] and recruited physician Dr. Hobbs, [21] who made a presentation to the Kentucky P&T Committee regarding Aceon. Ex. 346-347. Prior to the meeting, SPI sent the Committee an Aceon dossier replete with off-label information about Aceon, including the PROGRESS study. Ex. 370. Dr. Hobbs told the Committee that Aceon has an indication for vascular compliance, despite the fact that it does not. Ex. 348 at 2906. Dr. Hobbs discussed PROGRESS and even claimed *multiple times* that the study was free from bias, despite the fact that it was funded by Servier, the company that sold the rights to market Aceon in the US to SPI. *Id.* at 2902, 2907; Ex. 349 at 52. Dr. Hobbs also gave the Committee SPI's diabetic kidney pitch. Ex. 348 at 2903-2906. SPI's coached physician succeeded in convincing the Committee of these purported benefits: the Committee voted to keep Aceon free from prior authorization requirements. Exs. 219, 272.

Kentucky implemented a PDL in 2002. Ex. 288 at 295 (citing HB 103 (2002)). In 2002 and 2003, Aceon was "covered without restrictions." Exs. 272, 249 at 72. In 2004, according to a PDL produced by SPI, Aceon was also available without prior authorization. SPI RMPSJ Ex.

[21] Dr. Hobbs also assisted with training SPI's sales force regarding Aceon and AndroGel at the March 2003 POA meeting. SOLCID157355-64 at 57.

223; Ex. 350 at 45. From 2005 to 2007, Aceon became non-preferred. SPI RMPSJ Exs. 207-222. Utilization increased from 2000 to 2005 but plummeted in 2006 when Kentucky implemented prior authorization. Based on the evidence and Medicaid utilization Kentucky reimbursed Aceon without administrative controls from 2000 to 2004. Kentucky's Medicaid program is also a good example of a multi-year transition period to implement PDLs, which in this case lasted from 2002 to 2005. It is clear that SPI targeted and improperly influenced P&T decision makers both prior to, and during, that transition period, belying SPI's argument that PDLs alone should be used as a bright line rule for reimbursability.

5. Maryland

SPI's documents reflect the fact that Aceon was a Medicaid "approved" drug in 2000. Ex. 48. In 2002, Aceon was covered with no restrictions. Ex. 249 at 72. Aceon's status was a result of deliberate decisions by Maryland's Medicaid decision makers, which did impose restrictive measures on other drugs. *See, e.g.*, Ex. 257 (Maryland Prior Authorization form for AIDS Wasting Syndrome drug). Certainly aware of such restrictions, and not content with its "approved drug" status, SPI's 2002 Aceon Business Plan included the objective of increasing Aceon's "unrestricted reimbursement status," which SPI would accomplish by leveraging the PROGRESS data and utilizing Medical Liaisons and Opinion Thought Leaders to "focus on getting [the] stroke message" to managed care decision makers through presentations and face-to-face meetings. Ex. 282 at 410-11; *see also* Ex. 186 at 88 (reflecting lobbying efforts). Aceon's efforts pre-dated Maryland's implementation of a PDL in 2003. Ex. 288 at 295. As it turns out, Aceon became preferred from 2003 to 2005. SPI MSJ Exs. 246-250. From 2005 to 2007, Aceon became preferred, then non-preferred, each year. SPI MSJ Exs. 242-245. *See also* Ex. 201. Utilization went up from 2000 to 2004, and stayed stable in 2005, before plummeting in 2006.

Based on the evidence and Medicaid utilization, Maryland reimbursed Aceon without administrative controls in 2000, 2002-2004, and then for portions of 2005-2007. It is also clear that Maryland made decisions regarding prior authorization prior to the existence of PDLs.

6. Mississippi

SPI's documents reflect that in 2000, Aceon was a Medicaid "approved" drug in Mississippi. Ex. 48. This was before Mississippi's implementation of PDLs. In September 2001, as Mississippi prepared to implement a PDL in order to achieve Medicaid cost savings, SPI worked to oppose prior authorization and Mississippi's proposed restrictive formulary by obtaining a "schedule of meetings & agenda and formulary appeal process and work through established internal procedures to examine risks, pursue opportunities and alert field leaders." Ex. 193 at 76. In order to help Mississippi's Medicaid agency save costs without using prior authorization, SPI hired Don Muse to do studies identifying cost savings. *Id*. at 77. Senior Government Affairs Representative [redacted] noted in a memorandum that "the agency is receptive to Muse's data," and even though the Medicaid agency is still considering expanding the scope of its Pharmacy Benefits Manager's (PBM) responsibilities to achieve more savings, "the data might help loosen some of the restrictions if less money is on the table." Ex. 193 at 77. SPI's efforts paid off.

In 2002, Mississippi's Medicaid program covered Aceon without prior authorization. Ex. 249 at 72; Ex. 53 at 71; Ex. 60 at 89. Furthermore, in February 2003, SPI Regional Business Director [redacted] characterized Aceon's formulary status in Mississippi as "user friendly" as opposed to "challenging," meaning that Aceon did not require prior authorization. Ex. 53 at 70. Utilization grew from 2000 to 2003. Finally, Mississippi implemented a PDL in 2004. Ex. 288 at 296 (citing HB 1434 (2004)). From 2004 to 2005, utilization dropped from

$202,629 to $73,064. *Id*. Based on the evidence and utilization, Mississippi reimbursed Aceon without prior authorization from 2000-2003.

7. New York

According to New York, from 1999 to 2001, New York had an open formulary with no prior authorization. Ex. 298. From 2002 to 2005, the ACEI class was not on PDL, but New York Medicaid reimbursed Aceon without prior authorization. Ex. 298; Ex. 249 at 72; Exs. 290, 272, 183, 184, 291, 201 at 72. In 2005, New York authorized the creation of a "preferred drug list within Medicaid." Ex. 288 (citing S 3668 (2005)). This underscores the inherent problem with making PDLs, or any other list, a bright line rule for reimbursement. Setting aside that observation, utilization skyrocketed in 2002, and stayed stable through 2005, before plummeting in 2006. App'x A. This is consistent with the evidence, which shows that Aceon was available without prior authorization—despite not being listed on a PDL—from 2002 to 2005. In 2006, Aceon became non-preferred and stayed non-preferred through 2007. RMPSJ Exs. 380-382.

8. Wisconsin

Wisconsin reimbursed Aceon from 1999 to 2005 without prior authorization. Ex. 79. In February 2000, according to its internal documents, SPI was concerned about Wisconsin's tightening of restrictions on ACEIs and represented that it would, "work to program administrators [sic] to let ACEON stay regular approval." Ex. 48. On February 18, 2000, SPI informed the Wisconsin Department of Health and Family Services that it was going to send a physician to present the "therapeutic advantages of Aceon." Ex. 285. SPI's efforts were fruitful. From 2000 through August 2005, Aceon remained reimbursable free of prior authorization requirements. Exs. 79, 106, 183, 200 at 71. Indeed, utilization grew from 2000-2005 and plummeted in 2006 after Aceon became non-preferred, requiring prior authorization. Ex. 79. In

2003 the Wisconsin 2003-2004 budget bill provided for a Medicaid PDL. Ex. 288 (citing SB 44). Based on the evidence and Medicaid utilization, Wisconsin reimbursed Aceon without prior authorization from 1999-2005. It is also clear that Wisconsin was making coverage decisions prior to PDLs.

D. SPI's Bright-Line PDL Rule Is Unsupported as to Both Relators' Federal and State Claims.

The RMPSJ does not indicate whether SPI seeks summary judgment on both state and federal claims. It is notable that states have been especially clear that gaining formulary status through misrepresentations violates false claims statutes. For example, the National Association of Medicaid Fraud Control Units, in announcing settlement of an off-label case, summarized the states' position regarding reimbursability, stating that false claims are submitted where drug companies make "false representations, [for instance] concerning the safety of [a drug] to [states'] Medicaid program[s] and the Medicaid program[s] rel[y] on that information to [their] detriment in making formulary and prior authorization decisions with respect to the drug." Ex. 83.

Texas took the same position in *State of Texas, ex rel. Allen Jones v. Janssen LP*,[22] which, like this case, encompassed periods before the adoption of a P&T Committee in Texas. In its complaint in intervention, Texas explained that during that time, Texas's DUR Board had the authority to impose various administrative controls on undesirable drug utilization, including prior authorization, and it used that authority as it saw fit. Ex. 68. The State of Texas took the position that the manufacturer's misrepresentations to Medicaid caused the DUR Board to refrain from using such controls, whereas the DUR Board would otherwise have acted to stem that drug's utilization. *Id.* Therefore, as to Texas and other states, claims premised on false

[22] *State of Texas, ex rel. Allen Jones v. Janssen LP*, No. D-1GV-04-001288, Texas Dist, Travis Co.).

representations made to decision makers, including P&T Committees and DUR Boards, are actionable. As a result, the dispositive issue, during any period, in a particular state, is whether SPI improperly influenced Medicaid decision-makers to obtain or maintain coverage for the drugs at issue without prior authorization or other restrictions. As a result, neither the non-existence of a PDL nor a drug's exclusion from a PDL, alone, is dispositive. The states' position on such fraudulent inducement is applicable to the federal statute.

SPI's sales force pushed for Medicaid (and other government program) access in part by targeting P&T Committee members aggressively and with off-label messages and heavy spending. 5AC ¶¶ 281–289. To the extent that SPI bought its way onto government formularies and PDLs by off-label marketing and falsities, the falsity of a claim obviously cannot turn on mere reimbursability, both at the federal and state level. This is no different than the well-established case law on fraud on the FDA, which rest on the same premise of misrepresentations causing a device or drug to become or remain eligible for payment: a false claim includes one that became eligible for payment only through deception.[23] Relators already advanced this argument in response to the 5AC MTD and the Court agreed with Relators.

E. CONCLUSION

SPI posits that the existence or non-existence of a PDL and the mere listing or non-listing of a drug as preferred are dispositive of Relators' claims. As discussed above, that is incorrect. The state-by-state descriptions included above demonstrate that states used administrative controls, such as prior authorization, DUR Boards, and formularies, *in addition to* PDLs to

[23] See *U.S. ex rel. Krahling v. Merck & Co., Inc.*, No. CIV.A. 10-4374,2014 WL 4407969 (E.D. Pa. September 5, 2014) (Merck omitted information on the true efficacy of mumps vaccine after obtaining efficacy data at odds with submissions to FDA at time of approval; continuing to sell vaccine was contingent on disclosure of data), Order in *U.S. ex rel. Bui v. Vascular Solutions, Inc.*, Cause No. A-10-CA-883-SS (W.D. Tex. Mar. 6, 2013) (slip. Op. at 5, 8) (laser device marketed for veins not within label plausibly pled a false claim because false belief that use was approved could have clouded physicians' judgment); see also *U.S. ex rel. Feldman v. Van Gorp et al.*, 697 F.3d 78, 97 (2d Cir. 2012) (FCA liability applied where NIH paid grant funds after grantees began misrepresenting use of funds).

determine reimbursement status. SPI's argument that because formularies were allegedly not "CMS-approved" they are not formularies is likewise fanciful. SPI's employees and States referred to their mechanism for controlling reimbursements as "formularies." Because SPI forwards no other facts but these, evidence is insufficient to demonstrate no material dispute in those states. In addition, Relators have conceded the drugs, and periods for the few states that had no practice of employing administrative tools, and Relators have also conceded the drugs, states, and periods for which administrative tools appear to be in place. As to the remaining States and periods, Relators respectfully ask the Court to deny the RMPSJ.

Respectfully submitted,

BERG & ANDROPHY

By: */s/ Maria-Vittoria G. Carminati*

Joel M. Androphy
State Bar No. 01254700
Sarah M. Frazier
State Bar No. 24027320
Rachel L. Grier
State Bar No. 24055592
Maria-Vittoria G. Carminati
State Bar No. 24065007
Janis G. Gorton
State Bar No. 24071063
3704 Travis Street
Houston, Texas 77002
(713) 529-5622—Telephone
(713) 529-3785—Facsimile
ATTORNEYS FOR RELATORS JOHN KING AND TAMMY DRUMMOND

CERTIFICATE OF SERVICE

I certify that a true and complete copy of the Relators' Response to Solvay Pharmaceuticals, Inc.'s Renewed Motion for Partial Summary Judgment was served on October 28, 2014, on the following counsel as follows:

Via ECF w/ Exhibits & Email w/o Exhibits
Via Hand-Delivery w/ Exhibits
Bruce D. Oakley
Hogan Lovells
700 Louisiana Street, Suite 4300
Houston, Texas 77002
Tel.: (713) 632-1435
Fax: (713) 583-8909
Email: bruce.oakley@hoganlovells.com

Via ECF w/ Exhibits & Email w/o Exhibits

Jonathan L. Diesenhaus (pro hac vice)
Jessica L. Ellsworth (pro hac vice)
Hogan Lovells
555 Thirteenth Street, NW
Washington, DC 20004
Tel.: (202) 637-5600
Fax: (202) 637-5910
Email: jonathan.diesenhaus@hoganlovells.com
Email: jessica.ellsworth@hoganlovells.com

Andrea W. Trento
Hogan Lovells
100 International Drive
Suite 2000
Baltimore, MD 21202
Tel.: (410) 659-2700
Fax: (410) 659-2701
Email: andrea.trento@hoganlovells.com

/s/ Maria-Vittoria G. Carminati
Maria-Vittoria G. Carminati